

Exhibit No 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO THE FOLLOWING CASE:

Keeton v. Ethicon, Inc., et al.

Civil Action No. 2:13-cv-24276

ORDER

Pending is Plaintiff's Petition to be Paid from the Common Benefits Fund, *First Common Benefits Fund Invoice* by Lana C. Keeton December 28, 2016, filed December 29, 2016. [ECF No. 33]. In the Petition, the *pro se* plaintiff, Lana Keeton, seeks the court's approval for payment from the Common Benefit Fund in the amount of \$732,000 for "legal work performed for the benefit of the Plaintiffs in MDL 2327." [ECF No. 33-1, p. 1]. Pursuant to PTO No. 211, the court established the Fee and Cost Committee ("FCC") and appointed members to serve on the FCC. The FCC's responsibilities include making recommendations to the court for reimbursement of costs and apportionment of attorneys' fees for common benefit work and any other utilization of the funds.

Plaintiffs' Petition must first be submitted to the FCC for consideration and recommendation. It is **ORDERED** that Plaintiff's Petition [ECF No. 33] is **DENIED** without prejudice.

The Clerk is directed to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: January 4, 2017



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit No 2

LANA C. KEETON

CURRICULUM VITAE

Truth in Medicine - Med Device Expert LLC

Device Expert . Legal Consultant . Expert Witness . Patient Advocate

901 Pennsylvania Avenue, suite 3-423, Miami Beach, Florida 33139

(305) 671-9331 phone (305)342-8002 & (786)566-7780 cell phones (800)509- 9917 fax

lanakeeton@meddeviceexpertllc.com

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MEDICAL DEVICE EXPERT

EXTENSIVE IN DEPTH RESEARCH ON POLYPROPYLENE AND OTHER FOREIGN BODY POLYMERS USED TO MANUFACTURE SYNTHETIC SURGICAL MESH INCLUDING:

- *Mesh has never been inert
- *Degradation and decomposition are inherent to the manufacturing process
- *Physical and chemical properties direct causation to wound healing complications of mesh in humans
- *Foreign body polymers have direct causation to autoimmune disease

Keeton invested more than 10,000 hours of research into the cause/effect of patient complications from synthetic and biologic surgical mesh focusing on physical and chemical properties of polymers with consideration for the overall short and long- term impact of these foreign bodies surgically implanted in the human body. Her knowledge and understanding of the wound healing process from surgical mesh implantation is critical to all medical devices whether implanted as surgical mesh or used to perform the surgical procedure itself. The wound must make the transition from acute inflammation to healing or it leads to chronic inflammation causing or exacerbating the disease process leading to various forms of autoimmune disease.

Keeton's legal work in Federal Courts against the behemoth Johnson & Johnson, Ethicon Inc as a Pro Se plaintiff and manufacturing expertise from 30 years as a steel broker laid the basis for her career as a seasoned medical device expert, legal consultant and an expert witness. This professional experience resulted in consulting contracts with Big Law personal injury law firms designing discovery, with universal interrogatories for certain products and manufacturing processes, causes of action, deposition preparation, and consultation and research on legal and scientific issues and FDA regulatory compliance by medical device manufacturers. Keeton trained personnel in these high profile law firms to understand FDA regulations to prosecute their Surgical Mesh lawsuits in the Pelvic Mesh Multidistrict Litigations in West Virginia. Keeton's trial strategy has been implemented with success in certain mesh bellwether trials. Keeton has an overall factual knowledge of the inherent defects in synthetic surgical mesh as related to the law unequaled by any other expert in the field of surgical mesh.

EXPERT WITNESS & LEGAL CONSULTANT

- 2012 to present extensive work in the Pelvic Mesh MDL's in the Southern District of West Virginia consulting Plaintiff's Steering Committee.
MDL No. 2327 | In Re Ethicon, Inc. Pelvic Repair System Prod Liability Litigation
MDL No. 2187 | In Re CR Bard, Inc. Pelvic Repair System Prod Liability Litigation
- 2010 to 2011 legal consultant, expert witness to individual attorney firms

ENTREPRENEUR/ STEEL BROKER

Keeton bought painted and bare galvanized and galvalume coils of steel to sell to original equipment manufacturers who roll-form steel coils into roofing and siding panels for metal buildings for over 30 years. Excellent knowledge of physical and chemical properties of steel and how they relate to the functioning of the finished product. Directly translates to physical and chemical properties and the manufacture of synthetic surgical mesh. Keeton's manufacturing expertise is unmatched due to her comprehensive knowledge of not only original equipment manufacturers but the steel production process at steel mills and the toll coating process at coil coaters across America where they coat bare metal with zinc and aluminum and/or paint it for use in pre-engineered metal buildings or residential housing. Specifications in the steel industry are very finite with very narrow tolerances and translate to the manufacture of polypropylene and other polymers. Owner of Florida based Lana C. Keeton LLC since 2001.

PRESIDENT AND FOUNDER - TRUTH IN MEDICINE INCORPORATED

Truth in Medicine is a nonprofit patient advocacy organization Keeton founded in 2008 to educate the public about the potential risks and complications from the implantation of synthetic surgical mesh into the human body. The organization also educates and supports patients who have already been harmed by surgical implantation of synthetic mesh.

Truth in Medicine has worked with key members of the U.S. Food and Drug Administration and specifically the Center for Devices and Radiological Health (CDRH) as a patient advocate since 2007. The organization **was instrumental in the FDA issuing warnings** on the serious risks and complications associated with the transvaginal placement of surgical mesh in October 2008 and a second much more serious Patient Health Notification issued by the agency in July 2011.

Truth in Medicine Focus at this time is to influence the CDRH to make better use of the FDA's current regulatory authority for greater patient safety. Keeton's work has been paid for from her own personal earnings without any financial support from hundreds of national law firms that have benefitted greatly from the soon to be over \$11 Billion dollars of Pelvic Mesh verdicts/settlements.

Keeton organized two national mesh-injured patient conferences, one in Washington, D.C. and the other in Ft Lauderdale, FL, which included nationally recognized speakers, a doctor's roundtable, brainstorming sessions, visits with members of Congress and a rally in front of the U.S. Capitol building.

February 2012

Invited by Consumers Union and Rep. Edward Markey (D-MA) to present to members of the press concerning the Sound Devices Act.

November 2011

Consulted with Public Citizen on its petition to have transvaginal mesh removed from the market.

Met with Union of Concerned Scientists – 2-day session to help prepare a White Paper on patient safety lapses within the FDA.

March 2012

Keeton invited by CDRH Director Jeff Shuren to present on panel at **FDA's** public meeting on MDUFA

Patient Consumer and Health Coalition of 20 different organizations, *Truth in Medicine* continues to work with the coalition, and has since 2008, to inform members of Congress about the inadequate use of patient safety provisions within the agency and to make changes to the antiquated 510(k) clearance process.

ON CAPITOL HILL:

Truth in Medicine and Keeton actively work with legislators on Capitol Hill on current legislation to strengthen medical device safety and impact legal litigation to stop Plaintiff abuse in Multidistrict Litigation. Particular focus is the current uninformed use of synthetic surgical mesh with a long term view to properly inform patients not only on synthetic surgical mesh, but on all permanently implanted medical devices.

Testimony advocating for patient safety within the FDA regulatory framework has been presented to the Institute of Medicine, various members of Congress, key personnel within the FDA/ CDRH and at *Truth in Medicine* patient conferences. Keeton's work has led to synthetic surgical mesh for pelvic organ prolapse repair being removed from the market by working within the current regulatory authority of the FDA/CDRH. She has expansive knowledge of FDA and CDRH regulatory authority relating to synthetic and biologic surgical meshes and medical devices as a whole.

INFLUENCED LEGISLATION:

Institute of Medicine – Review of FDA's 510(k) regulatory authority, *Truth in Medicine* was the only patient advocacy group whose recommendations were included in the final IOM report to the FDA July 2011.

CURRENTLY WORKING:

Truth in Medicine continues to work with members of Congress, the Senate Judiciary Committee and the House Judiciary Committee, to enlighten and inform members of Congress concerning key patient safety issues related to implanted medical devices that continue to severely harm and kill patients not resolved by over 100,000 lawsuits in the Southern District of West Virginia. The massive Pelvic Mesh multidistrict litigations simply perpetuated severe harm to women implanted with surgical mesh. Congress must pass legislation to protect Patient Plaintiffs from the highly flawed Health and Legal Systems that cause them so much physical, mental, emotional and financial harm.

AT THE FDA:

In person meetings: March 2, 2010 - November 3, 2010 – May 17, 2011 - November 17, 2011, August 22, 2014, September 5, 2018 - Continuing efforts with key senior personnel at the FDA's CDRH to make patient labeling mandatory for all implantable medical devices to be provided in a separate non-sterile package along with the Instructions for Use (IFU) and to remove synthetic surgical mesh from the market based on 87,000 adverse events reported on September 5, 2018.

PRO SE PLAINTIFF

Keeton's lawsuit against Johnson & Johnson/Ethicon/Gynecare Worldwide for defective synthetic surgical mesh product liability was filed in December 2005. It led to her work as a legal consultant and research analyst designing discovery and providing unique comparative analysis of wound healing complications in humans as they relate to the design, manufacture and surgical implantation of surgical mesh devices

MESH INJURED PATIENT

As a mesh-injured patient, Keeton understands the real life personal trauma resulting from serious synthetic mesh complications. Her near-death experience from necrotizing fasciitis followed her own mesh implantation in 2001. Keeton has endured repeated mesh removal surgeries over the last 2 decades.

RELATED EXPERIENCE**KK INTERNATIONAL BOXING PRODUCTIONS**

Licensed Boxing Promoter in the State of Florida, 1999 – 2001 promoting boxers from Argentina; Company closed due to near death from mesh implantation

EVENT PLANNER AND FUNDRAISER

Raised monies for various nonprofit organizations.

PROFESSIONAL MEMBERSHIPS – EDUCATION & HONORS

Member (past): American Chemical Society

Member: Alpha Delta Pi Sorority

Florida Bioethics Network Conferences 2010 – 2011 (CME certificates)

Texas Christian University: 1965-1967 Lollie S. Greene Scholarship

University of Texas at Austin: 1967-1969

High School: DAR Good Citizen of the year, National Honor Society, other honors, awarded scholarship to college, many other activities.

PERSONAL

- *Extensive knowledge of FDA and CDRH regulatory authority relating to synthetic and biologic surgical meshes and medical devices as a whole
- *Intellectually and Socially Passionate
- *Excellent Speaking and Presentation skills
- *High IQ and love of data result in Exceptional Analytical and Research skills
- *Creation of numerous databases from research into surgical mesh complications which include thousands of detailed records on mesh injured patients
- *Spanish - speak fluently and read/write with high proficiency

Native Texan, Daughter of a homemaker and cattle rancher who owned a meat packing company. I grew up on a farm with a large extended family. Love the outdoors, travel, and West Highland White Terriers

TRUTH IN MEDICINE INCORPORATED www.truthinmedicine.us.com

MED DEVICE EXPERT LLC www.meddeviceexpertllc.com

PERSONAL WEBSITE: www.lanakeeton.com

PERSONAL BLOG: www.theladyisachamp.blogspot.com

LEGAL ACTIVISM: www.plaintiffpoweredlaw.com

MESH ACTIVISM TIMELINE

December 21, 2005

Filed Pro Se Product Liability lawsuit vs. Johnson & Johnson/Ethicon/Gynecare Worldwide for defective Gynecare TVT Prolene polypropylene Bladder Suspension System

May 2006

Lana Keeton vs. Gynecare Worldwide removed to United States District Court for the Southern District of Florida; in Federal Court through October 2007

Spring 2007

Multiple successful motions to compel discovery from defendants – Have tremendous insight into manufacture, processing, distribution and marketing of all Johnson & Johnson/Ethicon/Gynecare synthetic surgical mesh products including Mersilene, Prolene, Gynemesh, UltraPro, etc.

April 2007

Hired Peter Schmitt, Textile Development Associates, a textile engineer as expert witness.

July 23, 2007

Court ordered Summary Judgment in favor of Ethicon/J&J based on procedural error. Failed to name my treating physicians, who were experts, as non-retained experts. Judge ruled unable to prove medical causation.

September 16, 2007

created Medical Mesh, a yahoo members only health group for mesh injured patients – over 8,000 posts moderated over 4 year period

September 27, 2007

Provided my expert witness reports to attorney firm demonstrating lack of substantial equivalence in the 510(k) clearance of the Gynecare TVT and scientific defects in synthetic surgical mesh. Later used by firm to win Mentor Obtape litigation June 2010.

June 2008

Truth in Medicine, a patient advocacy organization, organized in the State of California

June 16, 2008

First **FDA** Center for Devices and Radiologic Health (CDRH) Synthetic Mesh Conference Call

Dr. Daniel Schultz, Center Director CDRH

Dr. Murray Malin, Medical Officer Office of Compliance

Ann Ferriter, Network Leader

Betty Collins, Division Director- Office of Compliance

Tom Knott, Branch Chief Office of Compliance

Wayne Miller, CSO Office of Compliance

Harriet Albershiem, Public Health Advisor Office of Communication, Education and Radiologic Programs

Lori Bernato, Senior Regulatory Officer- Office of Compliance

Scott McNamee, Materials Engineer- Office of Compliance

Les Weinstein, Ombudsman CDRH

Roxolana Horbowyj, Medical Officer Office of Device Evaluation

Vicky Wolfhard, Executive Secretary CDRH

July 2008

Provided 300 pages of discovery re: failures of Gynecare TVT System to Murray Malin at the FDA. At the same time, the CDRH was clearing for sale the Gynecare Prolift mesh kit which had been on the market since 2005 without any clearance or authorization from the FDA

July 3, 2008

Conference call with Jim Shull and Dr. Murray Malin, **FDA** Medical Officer, Office of Compliance

July 21, 2008

Conference call with Jim Shull and Dr. Murray Malin, **FDA** Medical Officer, Office of Compliance

August 11, 2008

Conference Call with Dr. Murray Malin, **FDA** Medical Officer, Office of Compliance and Dr. Kimber Richter, Deputy Director of Compliance

July 2008

Met and consulted with attorney firm in San Francisco, CA advising them on the inherent defects of synthetic surgical mesh

September 2008

FDA'S CDRH conference call

September 2008

WPLG Channel 10 Miami ABC affiliate television interview

October 21, 2008

First **FDA** Public Health Notification warning of serious risks and complications of Transvaginal Mesh. 9 manufacturers

February 2009

CDRH conference call

May 2009

Truth in Medicine re-organized in the State of Florida

August 2009

Ken Goodman PhD collaboration to create Informed Consent Website, initially for synthetic surgical mesh and then to follow with other implanted medical devices; ongoing collaboration at the FDA/CDRH, Speaking at Truth in Medicine Annual Conferences; a tremendous asset to Truth in Medicine

September 25-26, 2009

First Annual Conference Truth in Medicine

"Surviving the Complications of Synthetic Surgical Mesh", Ft Lauderdale, FL

Friday - Ken W. Goodman, PhD, Director, Bioethics Program and Co-Director, Ethics Programs, University of Miami, Nancy Muller, Executive Director NAFC, Diana Zuckerman, President, NRC

Saturday - Doctors Roundtable: Dr. Dee Fenner, Dr. Cheryl Iglesias, Dr. G. Willy Davila, Cleveland Clinic Weston, Florida

February 25, 2010

WSVN Channel 7 Fox Affiliate Lana Keeton interview on pitfalls of synthetic surgical mesh for hernia repair, bladder suspension and pelvic organ prolapse

March 1, 2010

Testified as patient advocate at 1st Institute of Medicine (IOM) workshop on the 510(k)

March 2, 2010

Presentation at **FDA**, Silver Springs, MD to senior personnel on the FDA's Surgical Mesh Investigative Team:

Truth in Medicine Formal Requests to FDA/CDRH:

1. Issue a Public Health Notification warning of the serious risks and complications of Synthetic Mesh used for Hernia Repair
2. Informed Consent packaged in non-sterile packaging with package insert
3. Re-review of surgical mesh based on GAO's recommendations

4. Future Synthetic Surgical Mesh not be cleared through 510(k) process
5. Require Post Market Studies of Meshes already on the market
6. Warnings clearly demonstrating serious risks and complications, including death
7. Black box warning on all synthetic surgical meshes
8. Special Guidance Document on synthetic surgical mesh

How do we help protect patients?

1. Better Patient Education - Informed Consent - How the FDA/CDRH will play a vital role in this process.
2. Synthetic Surgical Mesh is an example of the inadequacies of the 510(k) approval process. How will we use the example of synthetic surgical mesh to facilitate the FDA's current review of the 510(k) process ?
3. Physical and Chemical Properties of Synthetic Surgical Mesh; Processing of the Mesh; Maintaining the Integrity of the Mesh; Biocompatibility of Mesh; Performance in Vivo
4. Going Forward: Questions without Answers. What to address first? Which should not be addressed at all? Which ones have already been answered?

March 10, 2010 Truth in Medicine Hospitality Suite, American Hernia Society, Orlando, FL – filmed patient and doctor interviews

June 14, 2010

Testified at 2nd IOM workshop on the **FDA's** 510(k); Organized group of mesh injured patients who also testified at IOM workshop; Meeting with Congresswoman Ileana Ros-Lehtinen on Surgical Mesh at her office in D.C. to discuss ongoing efforts of Truth in Medicine

August 2010

Attended 3rd and final IOM workshop on **FDA** 510(k) Clearance Process in Washington, D.C.

October 1, 2010

Truth in Medicine "Mesh Out" Rally on the National Mall in front of the Capitol Building

October 2, 2010

Second Annual Conference Truth in Medicine in Washington, D.C. *"Alternatives to Synthetic Surgical Mesh"*

Dr. Kevin Petersen, Summerlin Surgical Associates, Las Vegas, NV Ken Goodman, PhD, Professor & Director Bioethics Program, University of Miami, Miami, FL Shannon Brownlee, Author "Overtreated: Why Too Much Medicine is Making Us Sicker and Poorer", Washington, D.C.

November 3, 2010 Meeting

Presentation at **FDA**, Silver Springs, MD to the following senior personnel on the FDA's Surgical Mesh Investigative Team:

Jeffrey Shuren, MD, JD: Director of the Center for Devices and Radiological Health

Diane Mitchell: CDRH Assistant Director for Science, Office of the Center Director

Geetha Jayan: Network Leader, Office of the Center Director

James Saviola: Network Leader, Office of the Center Director

Bakul Patel: Policy Advisor, Office of the Center Director

Patricia Dillon: Staff Fellow, Office of the Center Director

Nilsa Loyo-Berrios: Branch Chief, Office of Surveillance and Biometrics
 Nasrin Mirsaidi: MDR Specialist, Office of Surveillance and Biometrics
 Cara Krulewitch: Lead Epidemiologist, Office of Surveillance and Biometrics
 Nancy Pressly: Acting Associate Division Director, Office of Surveillance and Biometrics
 Douglas Wood: Acting Division Director, Office of Surveillance and Biometrics
 Thomas Knott: Branch Chief, Office of Compliance
 Charles Anamelechi: Commissioners Fellow, Office of Compliance
 Murray Malin: Medical Officer, Office of Compliance
 Dora Vega: Medical Officer, Office of Compliance
 Xin Xie: Commissioners Fellow, Office of Compliance
 Wayne Miller: Consumer Safety Officer, Office of Compliance
 Paula Silberberg: Public Health Advisor, Office of Communications Education and Radiation Programs
 David Krause: Branch Chief, Office of Device Evaluation
 Colin Pollard: Branch Chief, Office of Device Evaluation
 Julia Corrado: Medical Officer, Office of Device Evaluation
 Jill Brown: Medical Officer, Office of Device Evaluation
 Martin McDermott: Biomedical Engineer, Office of Science and Engineering Laboratories

March 10, 2011

Testified at **FDA's** CDRH Town Hall Meeting, Irving, TX; organized group of mesh injured women who also testified Town Hall Discussion With the Director of CDRH and Other Senior Center Management
<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm239730.htm>

April 13, 2011

Attended Special Committee on Aging Congressional Hearing on Medical Devices in Washington, D.C.;
 Organized group of other mesh injured patients to also attend; Invited by Senator Kohl's office to put statement on Medical Device Patient Safety in the record

May 17, 2011

Truth in Medicine hosted Capitol Hill Briefing with Dr. Shlomo Raz as Keynote speaker. Other testimony by Lana Keeton, President and Founder, Truth in Medicine, Diana Zuckerman, NRC and Janet Holt, Regulatory Affairs Director, Truth in Medicine.

May 17, 2011

Truth in Medicine introduced Dr. Shlomo Raz to FDA's CDRH Director Dr. Jeff Shuren and other key senior personnel (see list below) involved in Surgical Mesh Investigative Team at the FDA in Silver Springs, MD. Made request direct to Dr. Shuren to please have ObGyn Advisory Panel meeting; Request was granted and meeting was held Sept 8/9, 2011. Presentation by Dr. Raz was a big precipitator of the July 13, 2011 Transvaginal Mesh Warnings because of questions presented to the CDRH personnel by Dr. Raz:

1. Dr. Raz is seeing systemic effects of mesh and provided illustrations.
2. Mesh is not inert, despite representations by industry to the contrary.
3. A "minimally invasive" procedure is causing permanent disability.
4. Interstim implant patients receive a card after surgery documenting the medical device implanted in them. Mesh implant patients should be provided the same.
5. Should mesh be considered a drug?
6. The MAUDE database is not user friendly for filing adverse event reports.

7. If Synthetic Mesh were a drug with at least 10 associated deaths, it would most likely already be off the market.

Attendees

Office of the Center Director:

Dr. Jeff Shuren, Director, Dr. Diane Mitchell, Rachel Turow, Geetha Jayan

Office of Device Evaluation:

Jill Brown, Becky Robinson, Joyce Whang, Dr. Julia Corrado, Colin Pollard, Herbert Lerner

Office of Surveillance and Biometrics: Cara Krulewitch, PhD, Nasrin Mirsaidi, Megan Gatski, Ozlem Topaloglu, Samantha Jacobs, Colin Anderson-Smits

Office of Compliance: Charles Anamelechi, Jason Brookbank

Office of Communication, Education, and Radiation Programs: _Paula Silberberg, Kemba Ford

July 13, 2011

FDA issues second Public Health Notification (PHN) on serious risks and complications of Transvaginal placement of synthetic surgical mesh. Keeton's work as a patient advocate through Truth in Medicine was instrumental in this PHN being issued and the basis for the thousands of lawsuits in Multidistrict Litigation in the Southern District of West Virginia and all across the United States in other MDL's and State Courts.

July 14, 2011

Participated in **FDA** Conference Call re: July 13, 2011 PHN on serious complications of Transvaginal Mesh

August 2011

IOM report issued re: FDA's 510(k) ; Truth in Medicine recommendations included; TIM recommendations were only patient advocate recommendations included in report

September 8/9, 2011

Testimony at **FDA's** ObGyn Advisory Panel Meeting on Synthetic Surgical Mesh

September 16, 2011

Testimony at **FDA** Institute of Medicine (IOM) Public Meeting – Recommendations Proposed in Institute of Medicine Report: Medical Devices and The Public's Health, the FDA 510 (k) Clearance Process at 35 years

November 14, 2011

Meeting with Nick Carome, M.D. at Public Citizen. Public Citizen filed a legal petition August 25, 2011 to have all mesh for Pelvic Organ Prolapse recalled immediately and completely and meetings with government officials in D.C.

Nov 15/16, 2011

2 day meeting of the Union of Concerned Scientists at George Washington University convening a group of experts to look at the FDA right now titled "FDA at a Crossroads". Margaret Hamburg, Commissioner of the FDA, keynote speaker. Day 2 was a closed session where we broke up into small groups and the *"insights generated during these small-group discussions will be summarized in a white paper offering formal recommendations to government decision-makers"*. See link below.

November 17, 2011

Meeting with the **FDA**/CDRH Surgical Mesh Investigative Team to present substantial new scientific research I have done showing mesh is not inert and the resulting autoimmune complications.

Nov 18/19, 2011

Invited Guest by Joleen Chambers, Founder, *Failed Implanted Medical Devices*, Dallas, TX 75201 <http://fida-advocate.blogspot.com/> Leadership Conference "It's All About You – Health and Wellness for Texas Leaders" presented by The Foundation for Women's Resources www.womensresources.org in San Antonio, TX

February 2, 2012

Partnership with Consumer's Union on Capitol Hill meeting with Congressmen and Senators and their staffers in multiple meetings over 3 days

March 28, 2012

Invited to participate on Stakeholder Perspectives Panel and make presentation at FDA Public Meeting on Medical Device User Fee Act (MDUFA III); Meeting at Hubert H. Humphrey Building in Washington, DC

April 20, 2012

Mass Torts Made Perfect Invited Patient Advocate Guest Panelist - Transvaginal Mesh Panel with attorneys Robert Price, Henry Garrard III and Amy Eskin

January 29, 2013

Invited Guest Lecturer at the UT Quest Osher Life Long Learning Institute at the University of Texas at Austin "Think You're Protected? You're Not. What Your Doctor Doesn't know and the FDA is Not Telling You."© Americans go to doctors, whom they trust, who perform surgery on them in accredited hospitals using FDA "approved" products. They believe in the system. Americans don't ask questions. They trust a system that actually betrays them. My journey as a surgical mesh injured patient led me to become a patient advocate, a legal consultant and a voice for those thousands of injured patients at the FDA, on Capitol Hill and in America's healthcare system.

April 2013

Keeton was a featured speaker at the University of Miami's, Florida BioEthics 21st Annual Conference on how patient advocates can impact decision-making at the FDA. This follows *Truth in Medicine's* success in influencing the issuance of the 2008 and 2011 Public Health Notifications by the FDA on the serious dangers and complications concerning the use of transvaginal mesh for the repair of pelvic organ prolapse or incontinence.

August 22, 2014

Private Meeting with **FDA**/CDRH senior personnel – Made presentation on Inherent Manufacturing Defects of Polypropylene manufactured into Synthetic Surgical Mesh to the following:

- **Benjamin Fisher, PhD, Toxicologist, Director**, Office of Device Evaluation (ODE), **Division of Reproductive, Gastro-renal, and Urological Devices (DRGUD)**

- **Honggang Wang, PhD**, *Toxicologist*, ODE/DRGUD/OGDB
 - **Irada Isayeva, PhD**, *Materials Engineer*, Office of Science and Engineering Laboratories (OSEL)
 - **Martin McDermott, PhD**, *Biomedical Engineer*, OSEL
 - **David Simon, PhD**, *Biomedical Engineer*, OSEL
 - **Elaine Blyskun**, *Biomedical Engineer*, **Chief**, Obstetrics and Gynecology Devices Branch, ODE/DRGUD/OGDB
 - **Sharon Andrews**, *Biomedical Engineer*, ODE/DRGUD/OGDB
 - **Becky Robinson, PhD**, *Biomedical Engineer*, ODE/DRGUD/OGDB
 - **Herb Lerner, MD**, *General Surgeon*, **Deputy Director**, ODE/DRGUD
 - **Diane Mitchell, MD**, CAPT, USPHS, Office of the Center Director, Center for Devices and Radiological Health (CDRH)
 - **Julia Corrado, MD**, *Ob/Gyn Medical Officer*, ODE/DRGUD/OGDB
 - **Angel Soler-Garcia, PhD**, *Microbiologist*, ODE/DRGUD
1. Irada Isayeva, PhD, *Materials Engineer*, Office of Science and Engineering Laboratories (OSEL), agreed with Ms. Keeton's presentation on polymers 100%.
 2. Julia Corrado, MD, *Ob/Gyn Medical Officer*, ODE/DRGUD/OGDB requested Ms. Keeton to please advise the attendees the difference between a suture and synthetic surgical mesh, which she did.
 3. Benjamin Fisher, PhD, *Toxicologist*, **Director**, Office of Device Evaluation (ODE), Division of Reproductive, Gastro-renal, and Urological Devices (DRGUD) ask for additional info on male sterility from polypropylene hernia mesh and requested Ms. Keeton in the future to video the presentations she made for later use by the FDA.

September 5, 2018 Meeting with **FDA/CDRH** senior personnel – Made presentation on “*The Intersection of Medicine and Law*” submitting 87,000 unreported adverse event reports for Pelvic Mesh to: George Gibeily, Ann Ferriter, Sharon Andrews, Irada Isayeva, Benjamin Fisher, Marsha B. Henderson. Erin South, Terri Cornelison. Aron Yustein, Charles Viviano, Mark Kreitz, Joann Fujikawa, Catherine Ricketts, Glenn Bell, Cesar Perez, Abiy Desta and Ken Skodacek.

February 12, 2019

Public Speaker at FDA's OBGyn Panel meeting on Surgical Mesh for Pelvic Organ Prolapse. Keeton called for all Pelvic Mesh to be recalled due to 87,000 unreported adverse event reports which had not been filed due to Plaintiff's Attorneys in Multi District Litigation. Results: FDA denied FDA approval of any and all POP meshes undergoing Pre-Market Approval. Surgical Mesh recalled in various other countries by various manufacturers.

MEDIA TIMELINE

September 17, 2008

ABC affiliate Miami FL television interview Lana Keeton <http://www.local10.com/video/17492050/index.html>

May 4, 2009 “*Suffering In Silence From A Medical Device - Surgical Mesh (Part 4)*” by Jane Akre in Legal Examiner – Injury Board.com

July 4, 2009

"Watching Over the Medical Device Industry" by Jeanne Lanzer - Lana Keeton interview in British Medical Journal | 4 July 2009 | Volume 339

February 25, 2010

Lana Keeton on camera interview on the work of her organization at the FDA and in Washington, D.C.
<http://www.wsvn.com/features/articles/medicalreports/MI144678/>

September 2010

"Busted! Why isn't the FDA protecting us?" by Jeanne Lanzer and Shannon Brownlee, Readers Digest

November 2010

"Reckless Medicine" by Jeanne Lanzer and Shannon Brownlee
<http://discovermagazine.com/2010/nov/11-the-problem-with-medicine-don.t-know-if-most-works>

December 27, 2010

"Humility & Medicine" MyJobScope INSIDE THE WORLD OF MEDICAL DEVICE SALES & MARKETING
www.myjobscope.com <http://www.myjobscope.com/tag/o-r/>

May 21, 2011

"Medical Device Expert Explains DePuy Hip Failure" By Jane Mundy
<http://www.lawyersandsettlements.com/articles/depu-hip-replacement-recall/interview-depu-hip-replacement-3-16650.html>

July 14, 2011

WSVN FOX Affiliate Channel 7 Miami television interview Lana Keeton FDA: Pelvic Mesh for Women Riskier Than Thought <http://www.foxnews.com/health/2011/07/14/fda-pelvic-mesh-for-women-riskier-than-thought/>

JULY 14, 2011

[NEWSMAXHEALTH.COM](http://www.foxnews.com/health/2011/07/14/fda-pelvic-mesh-for-women-riskier-than-thought/) FDA: PELVIC MESH FOR WOMEN RISKIER THAN THOUGHT

July 15, 2011

CBS INTERVIEW television interview Lana Keeton: <http://www.wcax.com/story/15090619/a-warning-about-pelvic-mesh>

July 22, 2011

"Transvaginal Mesh Is Life-Threatening" By Jane Mundy for Lawyers and Settlements.com
<http://www.lawyersandsettlements.com/articles/transvaginal-mesh-tvt-sling/interview-tvt-sling-transvaginal-mesh-16878.html>

January 4, 2012

"FDA Orders Safety Studies for Vaginal Implants Made By J&J and C.R. Bard" by Alex Nussbaum and David Voreacos - Bloomberg interview

June 4, 2012

Another victory due in part to Lana Keeton's efforts as a Patient Advocate – *"J&J Tells Judge It Will Stop Selling Vaginal Mesh Implants"* By Alex Nussbaum and Jeff Feeley

October 18, 2012

Lana Keeton interview online, *"Mesh Injured Patient and Patient Advocate"*, by Jane Mundy for Lawyers and Settlements.com

February 26, 2013

Jury awards \$3.35 million in vaginal mesh case against Johnson & Johnson by Reuters.

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<http://www.sec.gov/Archives/edgar/data/1100962/000110096212000029/endorp-9302012x10q.htm>

For a complete list 2013 – 2019 of Keeton's extensive work that has pushed the topic of Pelvic Mesh to become a major conversation worldwide as the massive harm caused by Pelvic Mesh goes unchecked, please contact Ms. Keeton at LanaKeeton@MedDeviceExpertLLC.com. 08/21/2019